

**Department of Veterans Affairs (VA)**  
**Office of Research and Development (ORD)**  
**Clinical Science Research and Development Service (CSR&D)**  
**Minutes of the Cooperative Studies Scientific Evaluation Committee (CSSEC)**

The meeting was held at the St. Gregory Hotel, Washington, DC, on Wednesday, January 7, 2009. The Chair, George Machiedo, MD, presided.

**CSSEC Members Present:**

George Machiedo, MD - Chair

Barry Davis, MD, PhD

Michael Domanski, MD

Theodore Karrison, PhD (via teleconference)

Sheryl F. Kelsey, PhD

Karl Kieburtz, MD, MPH

Laura Mauri, MD, MSc

**Other Attendees Present:**

Philip Katz, MD

David Kent, MD

Larry Meyer, MD, PhD

John Powers, MD

Todd Rosengart, MD (via teleconference)

George Triadafilopoulos, MD

Michael Weisman, MD

**VA Staff Present:**

David Burnaska

Jonathan Gurland

Grant Huang, MPH, PhD

Timothy O'Leary, MD, PhD

Kelli Potter

Mike R. Sather, PhD, FASHP

Stuart Warren, PharmD

**Study Proponents Present:** see attached agenda

Dr. Machiedo opened the general session at 8:05 AM. Dr. Huang, Deputy Director, VA Cooperative Studies Program (CSP), provided welcoming remarks and thanked participants for their time and effort reviewing the proposals. He noted that CSSEC has a new member, Dr. Mauri, and that Dr. Warren Browner has completed his term as a CSSEC member. He mentioned that a CSP study on deep brain stimulation (DBS), CSP #468, was published in the *Journal of the American Medical Association* that day and that it was garnering significant media attention.

Jonathan Gurland, from the VA Office of General Counsel, conducted the annual ethics training for CSSEC members. He described the roles of Special Government Employees, and discussed ethics laws and standards of conduct. Dr. Huang asked members to sign the certification form stating that they completed the ethics training.

Dr. O'Leary, Director, CSR&D, thanked participants for their time and efforts and provided a program update. He, too, mentioned the DBS study and its media attention. He described the congressional and media attention over the past summer from a CSP study on smoking cessation in veterans with post-traumatic stress disorder, CSP #519, and the lessons learned from that experience. He described transition efforts underway for a new Secretary of VA, as well as the VA research budget over the past few years and future funding expectations.

In addition, Dr. O'Leary described CSP's experiences utilizing the Central Institutional Review Board and considerations for changing the way CSP handles genetic sub-studies. He noted efforts underway in CSP to achieve ISO 9000 certification and efforts examining how to shorten the timeframe from the inception of an idea for a cooperative study through the conduct of the trial to the publication of findings.

Dr. Huang closed the public session of the meeting at 9:07 AM to begin the study review portion. Dr. Machiedo explained the review process to members: the reviewers would meet in executive session to give brief synopses of their comments on the proposals before the Committee; study proponents are then brought in, apprised of reviewer comments by Dr. Huang and asked to make brief presentations and responses to the Committee; an interactive discussion with the CSSEC follows. A closed Executive Session follows to discuss recommendations for the proposal and to score it.

Committee members were informed that the proceedings and recommendations pertaining to the review of research proposals are considered to be privileged and confidential information. They were also asked to complete a conflict of interest form.

The study review portion of the meeting proceeded as scheduled, with two new studies, a resubmitted study and a midterm/extension request reviewed.

*New Submissions:*

CSP #574 "Extend Steroid (in) CAP(e) (ESCAPE): A Randomized, Placebo-Controlled, Double-Blind Clinical Trial to Evaluate the Safety and Efficacy of Low-Dose Methylprednisolone in Hospitalized Veterans with Severe Community-Acquired Pneumonia"

CSP #573 "A Randomized Trial of Medical and Surgical Treatments for Patients with GERD Symptoms that are Refractory to Proton Pump Inhibitors"

*Resubmission:*

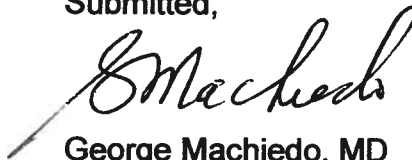
CSP #571 "Drug-eluting Stents vs. Bare Metal Stents In Saphenous Vein Graft Angioplasty (DIVA) Trial"

*Midterm/Extension Review:*

CSP #551 "Rheumatoid Arthritis: Comparison of Active Therapies in Patients with Active Disease Despite Methotrexate Therapy (RACAT)"

Dr. Huang proposed the next meeting be held in late spring or early summer 2009 and stated that CSP Central Office staff will contact CSSEC members to determine their availability and coordinate the next meeting. The meeting concluded at 3:20 PM on January 7, 2009.

Submitted,



George Machiedo, MD  
Chair CSSEC

**DEPARTMENT OF VETERANS AFFAIRS  
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE  
COOPERATIVE STUDIES SCIENTIFIC EVALUATION COMMITTEE (CSSEC)  
AGENDA**

January 7, 2009

The St. Gregory Hotel  
2033 M Street, NW  
Washington, DC 20036

**Wednesday, January 7, 2009**

8:00 – 8:20 AM      Opening of General Session & Welcoming Remarks  
*Timothy J. O’Leary, MD, PhD*  
*Director, Clinical Science R&D Service*

8:20 – 8:30 AM      Overview of Review Procedures  
*George Machiedo, MD*  
*CSSEC Chair*

8:30 – 9:00 AM      Ethics Training  
*Jonathan Gurland*  
*Office of General Counsel*

**1<sup>st</sup> Proposal**      **CSP #574 – “Extend Steroid (in) CAP(e) (ESCAPE): A Randomized, Placebo-Controlled, Double-Blind Clinical Trial to Evaluate the Safety and Efficacy of Low-Dose Methylprednisolone in Hospitalized Veterans with Severe Community-Acquired Pneumonia”**

9:00 – 9:15 AM      **Briefing Session**

9:15 – 9:35 AM      **Study Proponent Presentation**  
G. Umberto Meduri, MD – Principal Proponent  
Kelvin Lee, PhD – Study Biostatistician  
Mei-Chiung Shih, PhD – Senior Biostatistician  
Mark Smith, PhD – Health Economist  
Mark Holodniy, MD – Acting CSPCC Director

9:35 – 10:20 AM      **CSSEC Review**

10:20 – 10:35 AM      **Executive Session**

10:35 – 10:45 AM <b>Break</b>
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**2<sup>nd</sup> Proposal**      **CSP #551 – “Rheumatoid Arthritis: Comparison of Active Therapies in Patients with Active Disease Despite Methotrexate Therapy (RACAT)” – MIDTERM REVIEW**

10:45 – 11:00 AM **Briefing Session**

11:00 – 11:15 AM **Study Team Presentation**

James R. O'Dell, MD – Study Chair (via teleconference)  
Ed Keystone, MD – Study Co-Chair  
Mary T. Brophy, MD, MPH – Study Director  
Robert Lew, PhD – Study Biostatistician  
Ciaran Phibbs, PhD – Health Economist  
Louis Fiore, MD, MPH – CSPCC Director

11:15 – 11:45 AM **CSSEC Review**

11:45 – 12:00 PM **Executive Session**

12:00 – 12:30 PM	<b><u>Lunch (working lunch, if needed)</u></b>
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**3<sup>rd</sup> Proposal**      ***CSP #571 – “Drug-eluting Stents vs. Bare Metal Stents in Saphenous Vein Graft Angioplasty (DIVA)”***

12:30 – 12:45 PM **Briefing Session**

12:45 – 1:05 PM **Study Proponent Presentation**

Emmanouil S. Brilakis, MD, PhD – Principal Proponent  
Bob Edson, MA – Study Biostatistician  
Mei-Chiung Shih, PhD – Senior Biostatistician  
Mark Smith, PhD – Health Economist  
Mark Holodniy, MD – Acting CSPCC Director

1:05 – 1:50 PM **CSSEC Review**

1:50 – 2:05 PM **Executive Session**

2:05 – 2:15 PM	<b><u>Break</u></b>
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**4<sup>th</sup> Proposal**      ***CSP #573 – “A Randomized Trial of Medical and Surgical Treatments for Patients with GERD Symptoms that are Refractory to Proton Pump Inhibitors”***

2:15 – 2:30 PM **Briefing Session**

2:30 – 2:50 PM **Study Proponent Presentation**

Stuart Spechler, MD – Principal Proponent  
David Weiss, PhD – Study Biostatistician  
Patricia Sinnott, PT, PhD – Health Economist  
Joseph F. Collins, ScD – CSPCC Director

2:50 – 3:35 PM **CSSEC Review**

3:35 – 3:50 PM

**Executive Session**

4:00 PM

**MEETING ADJOURNMENT**